



Customer No.: 07278

Docket No.: 06727/0201826-US0

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Boaz Giron et al.

Serial No.: 10/506,872

Filed: April 25, 2005

For: BREATH COLLECTION SYSTEM

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- ☐ A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- ☒ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

Docket No. 06727/0201826-US0

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was either (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ ii. A check for the fee set forth in 1. 17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. Under 37 CFR 1.17(i) a check in the amount of \$180.00 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- ☒ A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated October 19, 2004 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.
- ☐ B. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☐ C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

[SERIAL NO. & FILING DATE].

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449 and/or PTO/SB/08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

☐ 3. Cite Nos. _____ are not in the English language. In accordance with 1.98(c), Applicant states:

- ☐ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.
- ☐ The requirement for a concise explanation of the relevance of any foreign language document is satisfied by the attached search report; citation of the documents cited in the search report shall not be construed as an admission that they are or are considered to be, material to patentability of the subject matter claimed herein (See MPEP §609).
- ☐ A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.
- ☐ A concise explanation of document(s) _____ can be found on the attached sheet.

☐ 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 in the preamble to the final rules; 1135 OG 13 at 20).

☐ 5. Other information being provided for the examiner's consideration follows:

[A/An _____ Search Report, dated _____, which issued during the prosecution of _____ Application No. _____ which corresponds to the present application.]

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited

document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

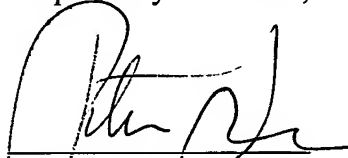
CROSS REFERENCE UNDER 37 C.F.R. (1.78 TO RELATED APPLICATIONS

Pursuant to 37 C.F.R. §1.78, Applicant notes that the above-identified patent application may be related to the following U.S. Patent Applications:

(1) U.S. Patent Application Serial No _____, filed _____.

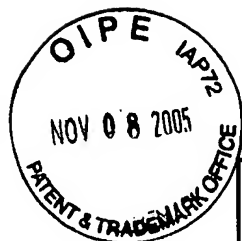
Early and favorable consideration is earnestly solicited.

Respectfully submitted,



S. Peter Ludwig
Registration No. 25,351
Attorney for Applicant(s)
DARBY & DARBY P.C.
P.O. Box 5257
New York, N.Y. 10150-5257
(212) 527-7700
(212) 527-7701 (Fax)
Attorney/Agent for Applicant(s)

November 4, 2005



PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO			Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Application Number	10/506,872-Conf. #4680
			Filing Date	April 25, 2005
			First Named Inventor	Boaz Giron
			Art Unit	N/A
			Examiner Name	Not Yet Assigned
			Attorney Docket Number	06727/0201826-US0
Sheet	1	of	2	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA*	US-4,723,435-A	02-09-1988	Huszczyk	
	AB*	US-5,787,885-A	08/1998	Lemelson	
	AC*	US-5,179,958-A	01/1993	Mault et al.	
	AD	US-Re 33,493	12/1990	Lee et al.	
	AE*	US-4,390,483-A	06/1983	Willems et al.	
	AF*	US-4,448,058-A	05/1984	Jaffe et al.	
	AG*	US-4,490,482-A	12-25-1984	Mathieu	
	AH*	US-4,639,432-A	01/1987	Holt et al.	
	AI*	US-4,680,956-A	07/1987	Huszczyk	
	AJ*	US-4,684,805-A	08/1987	Lee et al.	
	AK*	US-4,732,435-A	02/1988	Huszczyk	
	AL*	US-4,756,000-A	07/1988	Macken	
	AM*	US-4,757,512-A	07/1988	Macken	
	AN*	US-5,146,294-A	09/1992	Grisar et al.	
	AO*	US-5,300,859-A	04/1994	Yatsiv et al.	
	AP*	US-5,317,156-A	05/1994	Cooper et al.	
	AQ*	US-5,394,236-A	02/1995	Murnick	
	AR*	US-5,479,019-A	12/1995	Gross	
	AS*	US-5,486,699-A	01/1996	Fabinski et al.	
	AT*	US-5,501,231-A	03/1996	Kaish	
	AU*	US-5,543,621-A	08/1996	Sauke et al.	
	AV*	US-5,640,014-A	06/1997	Sauke et al.	
	AW*	US-5,657,750-A	08/1997	Colman et al.	
	AX*	US-5,747,809-A	05/1998	Eckstrom	
	AY*	US-5,818,580-A	10/1998	Murnick	
	AZ*	US-5,908,789-A	06/1999	Weckstrom	
	AA1*	US-5,944,670-A	08/1999	Katzman	
	AB1*	US-5,957,858-A	09/1999	Micheels et al.	
	AC1*	US-5,961,470-A	10/1999	Wagner et al.	
	AD1*	US-5,962,335-A	10/1999	Katzman	
	AE1*	US-5,964,712-A	10/1999	Kubo et al.	
	AF1*	US-6,067,989-A	05/2000	Katzman	
	AG1*	US-6,096,558-A	08/2000	Stock	
	AH1*	US-6,106,479-A	08/2000	Wunderlich et al.	
	AI1*	US-6,186,958-B1	02/2001	Katzman, et al.	
	AJ1*	US-6,437,316-B1	08/2002	Coleman et al.	

** Pursuant to the Notice issued by the United States Patent and Trademark Office dated October 19, 2004 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			
	1	WO-99/14576	3-25-1999	Oridion Medical Ltd.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/506,872-Conf. #4680
				Filing Date	April 25, 2005
				First Named Inventor	Boaz Giron
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	06727/0201826-US0

	2	GB-2 324 387-A1	10-21-1998	PARI GmbH		
	3	WO-00/67634	11-16-2000	Mault		
	4	WO-98/30888-A1	07-16-1998	Otsuka Pharmaceutical Co., Ltd.		
	5	EP-1 205 750-A2	05-15-2002	Amirav		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	6	CORNETTA, Angelyn M., et al., "Use of a [¹³ C]urea breath test for detection of gastric infection with <i>Helicobacter</i> spp in dogs", American J. Veterinary Res., USA, November 1998, Vol. 59, No. 11, p. 1364-1369.		
	7	SCHOMMARTZ, B., et al., "Significance of Diagnostic Parameters in [¹³ C]Octanoic Acid Gastric Emptying Breath Tests" Isotopes Environ. Health Stud., NL, 1998, Vol. 34, No. 1-2, pp. 135-143.		
	8	SHREEVE, Walton W., et al., "Test For Alcoholic Cirrhosis By Conversion of [¹⁴ C]- or [¹³ C]Galactose to Expired CO ₂ ", Gastroenterology, July 1976, Vol. 71, No. 1, pp. 98-101.		
	9	LOTTERER, E., et al., "The simplified ¹³ C-urea breath test - One point analysis for detection of <i>Helicobacter pylori</i> infection", Z. Gastroenterol., 1991, Vol. 29, pp. 590-594.		
	10	CHENG, Wu-Hsun, et al., "Technology development in breath microanalysis for clinical diagnosis", J. Lab. Clin. Med., March 1999, Vol. 133, No. 3, pp. 218-228.		
	11	PLEIL, J. D., et al., "Collection of a single alveolar exhaled breath for volatile organic compounds analysis", American Journal of Industrial Medicine", 1995, Vol. 28, pp. 109-121.		
	12	SPANEL, Patrik, et al., "Influence of water vapour on selected ion flow tube mass spectrometric analyses of trace gases in humid air and breath", Rapid Communications in Mass Spectrometry, 2000, Vol. 14, pp. 1898-1906.		
	13	PLEIL, Joachim D., et al., "Measurement of volatile organic compounds in exhaled breath as collected in evacuated electropolished canisters", Journal of Chromatography B, 1995, Vol. 665, pp. 271-279.		
	14	SCHUBERT, Jochen K., et al., "CO ₂ -controlled sampling of alveolar gas in mechanically ventilated patients", J. Appl. Physiol., 2001, Vol. 90, pp. 486-492.		
	15	NARASIMHAN, L. R., et al., "Correlation of breath ammonia with blood urea nitrogen and creatinine during hemodialysis", PNAS, April 10, 2001, Vol. 98, No. 8, pp. 4617-4621.		
	16	DUNN, C. D. R., et al., "Ammonia vapour in the mouth as a diagnostic marker for <i>Helicobacter pylori</i> infection: preliminary 'proof of principle' pharmacological investigations", British Journal of Biomedical Science, 2001, Vol. 58, pp. 66-75.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--



11-10-05

DFW

Application No. (if known): 10/506,872

Attorney Docket No.: 06727/0201826-US0

Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. _____ in an envelope addressed to:

EV 692134299 - us

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on November 8, 2005
Date

B.W. Lee

Signature

B.W. Lee

Typed or printed name of person signing Certificate

Registration Number, if applicable

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Information Disclosure Statement (4 pages)
PTO SB/08 (2 pages)
16 Documents
Return Postcard

BEST AVAILABLE COPY